K000884

JAN 1 9 2001

510(k) SUMMARY

SUBMITTED BY: BD BIOSCIENCES
7 LOVETON CIRCLE
SPARKS, MD 21152

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PREPARED: January 3, 2001

DEVICE NAME: BDProbeTec™ ET *Mycobacterium tuberculosis* Complex (ctb) Culture Identification Assay

PREDICATE DEVICES:
Biochemical tests
High-performance liquid chromatography
Gas liquid chromatography
Gen-Probe® AccuProbe® *Mycobacterium tuberculosis* (Mtb) Complex Culture Identification Test

INTENDED USE: The BDProbeTec™ ET *Mycobacterium tuberculosis* Complex (ctb) Culture Identification Assay, for use with the BDProbeTec™ ET System, utilizes Strand Displacement Amplification (SDA) technology to detect *IS6110* DNA to aid in the identification of *Mycobacterium tuberculosis* complex in acid fast growth.

The BDProbeTec™ ET *Mycobacterium tuberculosis* Complex (ctb) Culture Identification Assay can be used on suspect acid-fast colonies from solid media growth or with modified 7H9 broth (MGIT™ or BACTEC™ 12B) containing acid-fast bacilli.

DEVICE DESCRIPTION:

The BDProbeTec™ ET *Mycobacterium tuberculosis* Complex (ctb) assay is based on the simultaneous amplification and detection of target DNA using amplification primers and a fluorescent-labeled detector probe.

The SDA reagents are dried in two separate disposable microwells. The culture growth to be tested is initially processed to heat inactivate mycobacteria, lyse cells and denature DNA (heat treatment, alkaline buffer and sonication). This processed culture material is added to the Priming Microwell, which contains amplification primers, fluorescent labeled detector probes, and other reagents. After incubation, the reaction mixture is transferred to the Amplification Microwell,

which contains two enzymes (a DNA polymerase and a restriction endonuclease) necessary for SDA. The Amplification Microwells are sealed to prevent contamination and are incubated in a thermally-controlled fluorescent reader, which monitors the reaction for the generation of amplified products. Stored processed culture material must be re-heated using the BD Oven to ensure denaturation of DNA to allow access to the target region for binding of bumpers, primers and detector.

Each reaction co-amplifies and detects an Internal Amplification Control (IAC). The purpose of this control is to verify that proper conditions exist for amplification and to indicate lack of inhibition so that amplification could occur if target is present. The IAC target is a single stranded oligonucleotide containing a region of the IS6110 target sequence.

The identification of *M. tuberculosis* complex DNA is determined by the level of the BDProbeTec™ ET MOTA relative to pre-determined cutoff values. The MOTA score is converted to a qualitative result of positive, equivocal, negative or indeterminate.

DEVICE COMPARISON:

Table 1 summarizes the similarities and differences between the BDProbeTec™ ET *Mycobacterium tuberculosis* (ctb) Complex Culture Identification Assay and the predicate devices.

Table 1: Device Comparison - *Mycobacterium tuberculosis* complex Identification Systems

Feature	**BDProbeTec™ ET *Mycobacterium tuberculosis* Complex (ctb) Culture Identification Assay**	**Gen-Probe® AccuProbe® Mycobacterium Complex Culture Identification System (K896493)**	**Biochemical Methods**	**High-Performance Liquid Chromatography (HPLC) Methods**
Intended Use	The BDProbeTec™ ET *Mycobacterium tuberculosis* Complex (ctb) Culture Identification Assay, for use with the BDProbeTec™ ET System, utilizes Strand Displacement Amplification (SDA) technology to detect *IS*6110 DNA as an aid in the identification of *M. tuberculosis* complex in acid-fast culture growth. The ctb assay can be used on suspect acid-fast colonies from solid media growth or with modified 7H9 broth (MGIT or BACTEC) containing acid-fast bacilli.	The AccuProbe® Mycobacterium Tuberculosis Complex Culture Identification Test is a rapid DNA probe test which utilizes the technique of nucleic acid hybridization for the identification of *Mycobacterium tuberculosis* complex (TB Complex) isolated from culture. The TB Complex consists of the following species: *M. tuberculosis, M. bovis, M. bovis BCG, M. africanum*, and *M. microti.*	A battery of conventional tests for identification of a wide range of mycobacteria	Chromatographic method used to identify various mycobacteria species
Type of Assay	Amplified DNA Probe	Non-amplified RNA Probe	Biochemical	Chromatographic
Technology	SDA	Nucleic acid hybridization	Various	HPLC
Target	IS6110	16S ribosomal RNA	Not applicable	Mycolic acids
Detection format	Simultaneous amplification & detection	Hybridization followed by detection	Individual chemical reactions	Pre-determined patterns of mycolic acids
Qualitative or Quantitative	Qualitative	Qualitative	Qualitative	Qualitative
Amplification Control	Yes - Internal	Not applicable	No	No
Number of Controls / Run	Negative Control (1) Positive Control (1)	Negative Control (1) Positive Control (1)	At least one positive and one negative control per test	At least one known organism (positive control) and a carrier substance to monitor background (negative control)
Contamination Control Method	Closed System	Not applicable	Not applicable	Not applicable

Table 1: Device Comparison - *Mycobacterium tuberculosis* complex Identification Systems (cont.)

Feature	BDProbeTec™ ET *Mycobacterium tuberculosis* Complex (ctb) Culture Identification Assay	Gen-Probe® AccuProbe® Mycobacterium Complex Culture Identification System (K896493)	Biochemical Methods	High-Performance Liquid Chromatography (HPLC) Methods
Dedicated TB Laboratory Area	One room for culture processing in a biological safety cabinet; benchtop for amplification / detection	One room for culture processing in a biological safety cabinet; one room for hybridization / detection	One room for culture processing in a biological safety cabinet; benchtop for interpretation	One room for culture processing in a biological safety cabinet; benchtop for interpretation
Dried Reagents	Yes	Yes	No	No
Samples to be Tested	Growth from liquid and solid culture media	Growth from solid culture media	Growth from solid culture media	Growth from solid media

SUMMARY OF PERFORMANCE DATA:

ANALYTICAL STUDIES:

Precision:

Precision of the BDProbeTec™ ET ctb assay was demonstrated by testing a 24 member panel consisting of 3 low and 3 high positive samples of *M. tuberculosis* ATCC™ 27294 and 18 negative samples consisting of 3 low and 3 high positive samples each of *M. avium* ATCC™ 25291, *M. intracellulare* ATCC™ 13590 and *M. kansasii* ATCC™ 12478. The precision panel was run at two clinical sites and one internal site. Six runs were performed by each site on different days across a period of two weeks. Because no site-to-site or day-to-day variability occurred, the data were combined and presented in Table 2. Assay control failures were not observed in the precision study.

Table 2: BDProbeTec™ ET ctb Assay Precision Results

				Within day		Between day		Between site	
Sample	n	%Correct	Mean MOTA	SD	%CV	SD	%CV	SD	%CV
(-)	323*	97.5%†	564	3,326	-	870	-	0	-
Low (+)	53*	100%	58,273	6,570	11	2,293	4	5,802	10
High (+)	54	100%	56,153	6,005	11	4,209	7	7,522	13
IAC with (-)	323*	NA	53,939	7,645	14	5,117	9	5,882	11

* One of each negative and low positive sample was not reportable due to an error message on test report for those samples.

† The range of percent correct for the negative sample was 98.1% (105/107) for Site 1, 95.4% (103/108) for Site 2 and 99.1% (107/108) for Site 3.

Analytical Sensitivity:

The Limit of Detection (LOD) for the BDProbeTec™ ET ctb assay is defined as the minimum number of nucleic acid target that generate a MOTA score above 25,000 100% of the time by the system. This LOD was determined to be 500 copies per reaction of the target sequence *IS*6110. This insertion sequence can exist in *Mycobacterium tuberculosis* complex organisms in up to 23 copies per organism.

When 10 isolates (six *M. tuberculosis* and four belonging to the complex) were tested, the LOD was shown to be an average of 25 CFU per reaction, (346 CFU/mL). By species, the LOD was determined to be *M. tuberculosis* 302 CFU/mL, *M. africanum* 1,190 CFU/mL, *M. bovis* 276 CFU/mL, *M. bovis* BGG 188 CFU/mL and *M. microti* 460 CFU/mL. The lower limit of sensitivity for a positive AFB smear ranges from 500 to 10,000 CFU/mL.

Analytical Specificity:

One hundred twenty one (121) organisms, at concentrations of approximately 10^7 CFU/mL, were tested with the BDProbeTec™ ET ctb assay to assess specificity. These organisms, which may or may not be present in respiratory specimens, included 66 bacteria, 40 different species of non-tuberculous mycobacteria, seven yeasts and fungi, and nine viruses.

Three replicates of each organism were tested initially. If one or more of these replicates tested positive or equivocal, then the organism was retested in triplicate from another aliquot and the data combined for analysis. If more than one of the six results was positive or equivocal, then the organism was considered to be potentially cross-reactive. All replicates (3) of *M. tuberculosis* were positive as expected.

One of three replicates of *Flavobacterium meningosepticum* and *Mycobacterium avium* was indeterminate on initial testing. These were repeated and the results were negative.

One of three replicates was positive on initial testing for *Mycobacterium thermoresistibile* . One of three replicates was equivocal on initial testing for the following organisms; Influenza virus B, *Mycobacterium phlei*, *Prevotella oralis* and *Streptococcus* group C. Each organism was retested and all results were negative.

Contaminant Mixed-Growth Study:

The ability of the BDProbeTec™ ET ctb assay to detect target DNA in the presence of mixed organism growth in broth cultures was assessed. Organisms representing common breakthrough contaminants (*Pseudomonas aeruginosa* ATCC 27853, *Klebsiella pneumoniae* ATCC 33495, *Candida albicans* ATCC 10231, and *Corynebacterium* internal strain FH#10) as well as non-tuberculous mycobacteria (*M. fortuitum* ATCC 6841 and *M. avium* ATCC 25291) were each inoculated into BACTEC 12B and MGIT broth media and incubated to instrument positivity.

An aliquot (500 µL) of each of the growth positive broth cultures was seeded with approximately 100 organisms of *M. tuberculosis* and tested in triplicate. All cultures with *M. tuberculosis* added were BDProbeTec ™ ET ctb assay positive as expected. An aliquot (500 µL) of each of the growth positive broth cultures that were not seeded with *M. tuberculosis* were tested in triplicate. All of these cultures were BDProbeTec ™ ET ctb assay negative as expected.

Interfering Substances:

Different media were tested with the BDProbeTec™ ET ctb assay to determine what effect, if any, they had on the assay results. Each media was evaluated both in the presence and absence of target organism, for a total of 24 replicates at each target level. The liquid media tested were appropriately supplemented according to the manufacturer's instruction.

BACTEC™ 12B, BBL™ MGIT™ 4 mL, BBL™ MGIT™ 7 mL, Lowenstein-Jensen, Middlebrook 7H10 and Middlebrook 7H11 were tested in the external clinical evaluation and in an internal interfering substances study. In the absence of target organism, all replicates for each media were negative as expected. In the presence of target organism, all replicates for each media were positive as expected. No indeterminate results were observed.

BACTEC™ Myco/F Sputa, Middlebrook 7H9 broth, Middlebrook 7H11 Selective and Ogawa media were not tested in the external evaluation but were tested in the internal interfering substances study. In the absence of target organism, all replicates were negative as expected, except for Middlebrook 7H9 medium which gave one positive result. In the presence of target organism, all replicates for each media were positive as expected, except for Middlebrook 7H9 medium which gave one equivocal result. No indeterminate results were observed.

CLINICAL STUDIES:

The performance of the BDProbeTec™ ET ctb assay was evaluated in a multicenter study at four geographically diverse clinical sites. The BDProbeTec™ ET ctb assay was tested from both broth media and solid media culture of each specimen. Cultures included acid fast growth from 268 clinical isolates and 98 from stock acid fast strains. Once growth was observed in the culture system(s) and acid fast bacilli (AFB) was detected by smear, the BDProbeTec™ ET ctb assay was performed on each AFB positive culture. Primary broth cultures were assayed either within four days or up to thirty-six days following growth positivity.

A total of 905 BDProbeTec™ ET ctb assay results were generated. The BDProbeTec™ ET ctb results were determined to be positive, negative, equivocal, or indeterminate. Of the 905 results, 183 were non-evaluable. Therefore, a total of 722 BDProbeTec™ ET ctb assay results from culture were compared to the site's final identification of the acid fast culture growth (using non-amplified probe, biochemical, and/or HPLC testing). Of these results, 357 were from MGIT™ or BACTEC™ 12B media culture (250 primary clinical broth culture) and 365 were from solid media culture. The performance is presented by calculating the percent correct for the BDProbeTec™ ET ctb assay results obtained. A correct result was defined as BDProbeTec™ ET ctb assay reporting a *M. tuberculosis* complex culture as positive or reporting a MOTT culture as negative. Equivocal results are presented separately.

Table 3 shows the performance of the BDProbeTec™ ET ctb assay compared to final identification for the clinical isolates from primary broth culture by site.

Table 3

Organism	Site	n	ctb Result[1] P	N	E	Percent Correct	95% C.I.	Percent Equivocal	Median days[2] (min-max)
Mtbc	1	12	11	1	0	91.7 (11/12)	61.5-99.8	0.0	3.5 (0-7)
	2	23	23	0	0	100.0 (23/23)	85.2-100.0	0.0	7 (1-24)
	3	38	38	0	0	100.0 (38/38)	90.7-100.0	0.0	7.5 (5-25)
	4	14	14	0	0	100.0 (14/14)	76.8-100.0	0.0	9.5 (3-21)
	Total	**87**	**86**	**1**	**0**	**98.9 (86/87)**	**93.8-100.0**	**0.0**	**7 (0-25)**
MOTT[3]	1	47	0	47	0	100.0 (47/47)	92.5-100.0	0.0	3 (0-13)
	2	33	1	28	4	84.8 (28/33)	68.1-94.9	12.1	7 (1-24)
	3	44	4	39	1	88.6 (39/44)	75.4-96.2	2.3	8 (4-31)
	4	39	0	39	0	100.0 (39/39)	91.0-100.0	0.0	8 (2-36)
	Total	**163**	**5**	**153**	**5**	**93.9 (153/163)**	**89.0-97.0**	**3.1**	**7 (0-36)**

[1] P=positive, N=negative, E=equivocal

[2] Duration (in days) from broth culture positivity to day of processing for the BDProbeTec™ ET ctb assay presented as median with minimum- maximum range.

[3] The MOTT isolates are identified as *M. avium complex* (111), *M. gordonae* (24), *M. fortuitum* (7), *M. chelonae* (3), *M. kansasii* (3), *M. parafortuitum* (3), *M. scrofulaceum* (3), *M. abscessus* (2), *M. xenopi* (2), *M. avium complex/M. chelonae* (1), *M. non-chromogenicum* (1), *M. simiae* (1), *M. szulgai* (1), *Mycobacteria species not M. tuberculosis, M. avium complex, or M. kansasii* (1).

The false positive BDProbeTec™ ET ctb results were observed with the following MOTT organisms; *M. avium* complex, *M. non-chromogenicum* and *M. szulgai.*

Of the 87 primary broth cultures with Mtbc, 86 had a positive BDProbeTec™ ET ctb result. Eighty of these cultures had a positive BDProbeTec™ ET ctb result from the corresponding solid media culture. The remaining six had equivocal BDProbeTec™ ET ctb results from the corresponding solid media culture.

Of the 163 primary broth cultures with MOTT, 153 had a negative BDProbeTec™ ET ctb result. One hundred and fifty two of these cultures had a corresponding solid media culture. Of the 152 solid media cultures, 149 had a negative BDProbeTec™ ET ctb result.

Table 4 shows the agreement of the BDProbeTec™ ET ctb result with final identification for the range of days from culture positivity to processing of the clinical isolate broth cultures.

Table 4

Day Range from Positivity to Processing		ctb Result Percent Correct with Final ID	
	n	**Mtbc**	**MOTT**
< 4 Days	52	100.0 (11/11)	97.6 (40/41)[1]
4 –6 Days	54	93.8 (15/16)	94.7 (36/38)[2]
7 - 14 Days	103	100.0 (46/46)	89.5 (51/57)[2]
>14 Days	41	100.0 (14/14)	96.3 (26/27)

[1] One equivocal result
[2] Two equivocal results

Nine clinical isolates were subcultured from solid media into broth culture media (not included in Table 3). The final identification of eight of the broth subcultures agreed with the final identification of the original solid media culture. The BDProbeTec™ ET ctb result agreed with the final identification for all nine of these isolates for each media type.

Table 5 shows the BDProbeTec™ ET ctb results compared to final identification for the clinical isolates from solid media culture and/or subculture.

Table 5

Organism	Site	n	ctb Result[1] P	N	E	Percent Correct	95% C.I.	Percent Equivocal
Mtbc	1	13	11	0	2	84.6 (11/13)	54.6-98.1	15.4
	2	24	23	0	1	95.8 (23/24)	78.9-99.9	4.2
	3	39	36	0	3	92.3 (36/39)	79.1-98.4	7.7
	4	17	17	0	0	100.0 (17/17)	80.5-100.0	0.0
	Total	**93**	**87[2]**	**0**	**6[3]**	**93.5 (87/93)**	**86.5-97.6**	**6.5**
MOTT[†]	1	53	0	53	0	100.0 (53/53)	93.3-100.0	0.0
	2	33	0	33	0	100.0 (33/33)	89.4-100.0	0.0
	3	44	6	37	1	84.1 (37/44)	69.9-93.4	2.3
	4	44	0	44	0	100.0 (44/44)	92.0-100.0	0.0
	Total	**174**	**6**	**167[4]**	**1**	**96.0 (167/174)**	**91.9-98.4**	**0.6**

[1] P=positive, N=negative, E=equivocal

[2] Thirty-four isolates subcultured from liquid growth, thirty-two with paired liquid primary cultures -32/32 agreed with initial culture result.

[3] Three isolates subcultured from liquid growth, three with paired primary cultures-3/3 agreed with initial culture result.

[4] Ninety-six isolates subcultured from liquid growth, eighty-nine with paired liquid primary cultures -89/89 agreed with initial culture result.

[†] The MOTT isolates are identified as *M. avium* complex (118), *M. gordonae* (28), *M. fortuitum* (7), *M. chelonae* (4), *M. kansasii* (3), *M. parafortuitum* (3), *M. scrofulaceum* (3), *M. abscessus* (2), *M. xenopi* (2), *M. non-chromogenicum* (1), *M. simiae* (1), *M. szulgai* (1), Mycobacteria species not *M. tuberculosis*, *M. avium* complex, or *M. kansasii* (1).

The false positive BDProbeTec™ ET ctb results were observed with the following MOTT organisms; *M. avium* complex, *M. gordonae*, and *M. szulgai*.

Table 6 shows the BDProbeTec™ ET ctb results compared to final identification for the stock isolate cultures.

Table 6

Organism	Media Type	n	ctb Result[1] P	N	E	Percent Correct	95% C.I.	Percent Equivocal
Mtbc	12B	0	-	-	-	-	-	-
	MGIT	21	21	0	0	100.0 (21/21)	83.9-100.0	-
	Solid	21	20	0	1	95.2 (20/21)	76.2-99.9	4.8
MOTT[2]	12B	30	2	28	0	93.3 (28/30)	77.9-99.2	-
	MGIT	47	2	45	0	95.7 (45/47)	85.5-99.5	-
	Solid	77	1	76	0	98.7 (76/77)	93.0-100.0	-

[1] P=positive, N=negative, E=equivocal

[2] The MOTT isolates from 12B and MGIT are identified as *M. kansasii* (47), *M. avium* complex (23), *M. avium* complex/*M. kansasii* (6), *M. xenopi* (1). The MOTT isolates from solid media are identified as *M. kansasii* (51), *M. avium* complex (23), *M. avium* complex/*M. kansasii* (2), *M. xenopi* (1).

The false positive BDProbeTec™ ET ctb results were observed with the following MOTT organism;, *M. avium* complex and *M. kansasii.*

Overall performance of the BDProbeTec™ ET *Mycobacterium tuberculosis* Complex (ctb) Culture Identification Assay on the BDProbeTec™ ET System, is substantially equivalent[1] organism final identification determined by biochemical tests and/or HPLC/GLC methods that were in use prior to May 28, 1976 and to the Gen-Probe® AccuProbe® *Mycobacterium tuberculosis* (Mtb) Complex Culture Identification Test.

[1] The term "substantial equivalence" as used in this 510(k) notification is limited to the definition of substantial equivalence as found in the Federal Food, Drug and Cosmetic Act, as amended and as applied under 21 CFR 807, Subpart E under which a device can be marketed without pre-market approval or reclassification. A determination of substantial equivalency under this notification is not intended to have any bearing whatsoever on the resolution of patent infringement suits or any other patent matters. No statements related to, or in support of substantial equivalence herein shall be construed as an admission against interest under the US Patent Laws or their application by the courts.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN 1 9 2001

Ms. Colleen Rohrbeck
Regulatory Affairs Specialist
BD Biosciences
7 Loveton Circle
PO Box 999
Sparks, Maryland 21152-0999

Re: K000884
Trade Name: BDProbeTec™ ET Mycobacterium tuberculosis Complex (ctb) Culture Identification Assay
Regulatory Class: I reserved
Product Code: NDZ
Dated: December 1, 2000
Received: December 4, 2000

Dear Ms. Rohrbeck:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K000884

Device Name: BDProbeTec™ ET *Mycobacterium tuberculosis* Complex (ctb) Culture Identification Assay

Indications for Use:

The BDProbeTec™ ET *Mycobacterium tuberculosis* Complex (ctb) Culture Identification Assay, for use with the BDProbeTec™ ET System, utilizes Strand Displacement Amplification (SDA) technology to detect *IS6110* DNA to aid in the identification of *Mycobacterium tuberculosis* complex in acid fast growth.

The BDProbeTec™ ET *Mycobacterium tuberculosis* Complex (ctb) Culture Identification Assay can be used on suspect acid-fast colonies from solid media growth or with modified 7H9 broth (MGIT™ or BACTEC™ 12B) containing acid-fast bacilli.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Woodey Dubois

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K000884

(Optional Format 3-10-98)